

Cleanroom Test Equipment

CRE



Test equipment set for the qualification of cleanroom facility: Aerosol Generator ATM 228, Dilution System DIL 554, Laser Aerosol Particle Counter LAP 340, Sampling Probe SYS 529.

To ensure the highest product quality, cleanroom facilities are used in a variety of industries. Their testing is performed according to standardised procedures, which require both expertise, and appropriate equipment technology. Topas provides a cleanroom test equipment set that complies with relevant standards and is characterised by high product quality, robustness, easy handling and suitability for mobile use.

Applications

- qualification of cleanroom facilities, cleanrooms, operating rooms and safety cabinets

	confirmation of cleanroom class ISO 14644-1	filter leak test ISO 14644-3 B.7.3	recovery test ISO 14644-3 B.4
aerosol generator		X	X
dilution system		X	(X)
particle counter	X	X	X
sampling probe		X	
aerosol substance		X	X

Features

- optimised for mobile use
- low maintenance requirements
- compatible with alternative measurement technology
- fast service (device inspection, new calibrations, repairs)

Principle of operation

The leak test on the built-in filter system of a safety cabinet serves as an example to describe the function of the individual devices of the cleanroom test equipment set (see next page).

First, a test aerosol is generated with an aerosol generator ATM 228 and entered into the air flow of the safety cabinet. The upstream concentration of the test aerosol is reduced by a Topas dilution system DIL 554 and determined with a particle counter LAP 340. The rectangular sampling probe SYS 529 and a particle counter are used for scanning the filter for leaks in the downstream.

Details

Aerosol generation

The performance parameters of built-in filter systems are tested using aerosol generators, which produce a test aerosol in the size range of the Most Penetrating Particle Size (MPPS) in high concentration.

In Europe, Di-Ethyl-Hexyl-Sebacate (DEHS) is recommended for the qualification of cleanroom facilities. The generated aerosol droplets are in the range of MPPS and have a long lifetime. Visit the company website for further details on the ATM 228.



Specifications

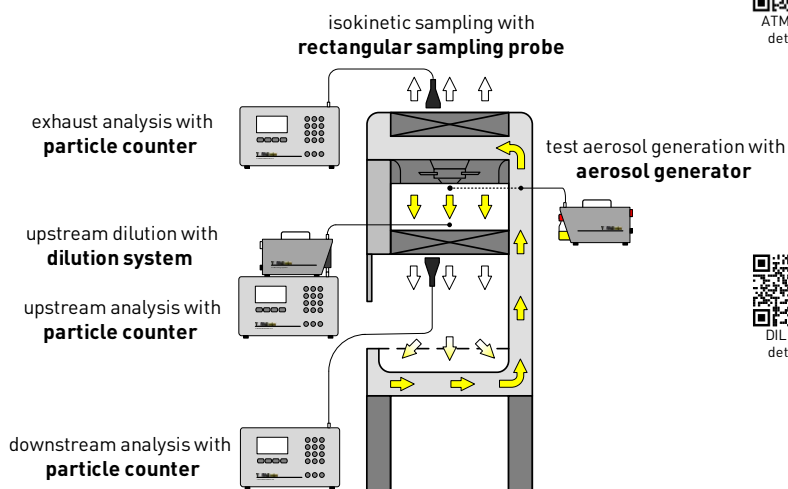


Illustration of the qualification procedure of a safety cabinet using the cleanroom test equipment set.

Aerosol dilution

A sufficiently high particle concentration in the upstream is necessary for the reliable detection of filter leaks in cleanroom facilities. According to [1], at least 3.5 million particles per 1 m³ of air are recommended. This test concentration exceeds the measuring range of commercially available cleanroom particle counters. Therefore, a dilution system is placed in front of the particle counter to enable the upstream to be examined.

The characteristics of suitable dilution systems are shown below:

specifications	DIL 554	DIL 550	VDS 562
total volume flow rate in l/min *	28,3 50 56,6	2,83 28,3	28,3 ... 100
dilution factor	1:100	1:10 1:100	variable
power supply	9V battery**	12 V DC power supply unit	12 V DC power supply unit

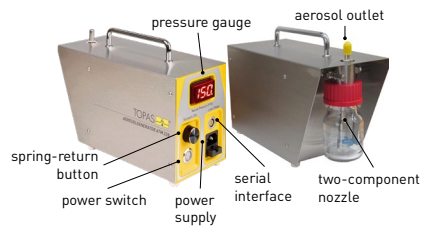
*) other configurations available on request

***) alternatively 12 V DC power supply unit

The advantages of the Topas dilution systems are their compatibility with alternative measurement technology, the absence of additional compressed air for dilution and the avoidance of exhaust air



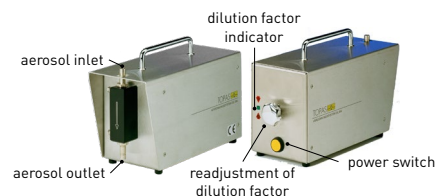
ATM 228 details



Atomizer Aerosol Generator ATM 228.



DIL 554 details



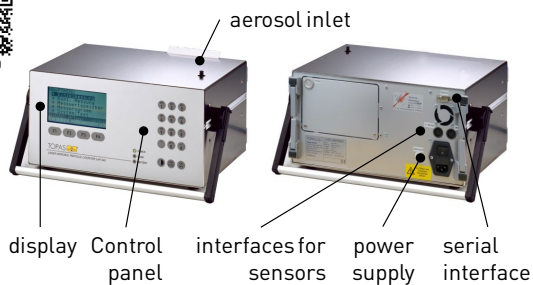
Dilution System DIL 554.

entering the cleanroom. Further features can be found on the company website.

Aerosol characterisation



LAP 340 details



Cleanroom particle counter LAP 340: front and back.

The LAP 340 is a mobile scattered-light single particle counter for measuring the particle number and size according to [1, 3, 6, 7, 8, 9].

specifications	LAP 340
particle size range in µm*	0,3-10
size classes	max. 16
volume flow rate in l/min	28,3

*) other configurations available on request

The advantages of aerosol particle counters compared to aerosol photometers result on the one hand from the good counting statistics due to the high measuring volume flow rate and on the other hand from the high detection sensitivity.

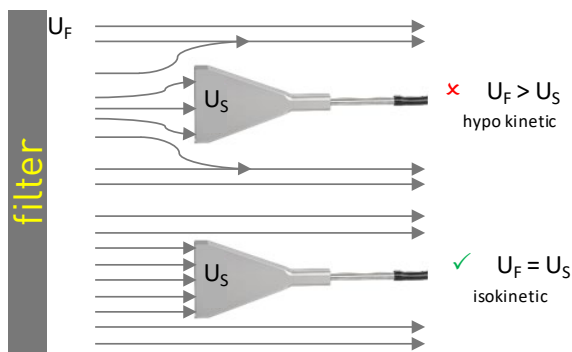


Specifications

The latter enables both the reliable detection of very small filter leaks and the use of low aerosol concentrations, which leads to a reduction in the filter loading by the test measurements [10].

Aerosol sampling

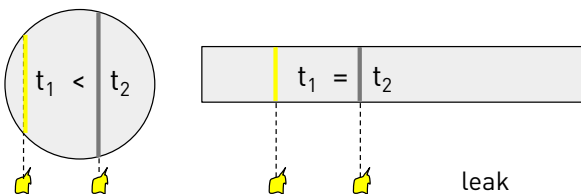
standard	requirements	sampling probe SYS 529
		layout for: 28,3 l/min
ISO 14644-3	recommended design: rectangle	✓
	$U_s = U_f \pm 20\%$ (isokinetic)	31 – 47 cm/s
VDI 2083-3	recommended design: rectangle	✓
	isokinetic sampling aspect ratio < 1:6	✓ 1:5,3 ✓



U_s ...flow velocity at probe inlet
 U_f ...flow velocity from the filter

Comparison of a hypokinetic and an isokinetic sampling using a rectangular probe.

Isokinetic sampling probes are required for leakage testing of installed filter systems in cleanrooms and cleanroom facilities. In the existing standards and guidelines, probes with rectangular cross-sections are recommended.



t...leakage residence time

Comparison of the leakage residence time (t) depending on the probe design.

The advantages of rectangular sampling probes are: i) constant leakage residence time, ii) precise scanning of filter corners and iii) reduced scanning times due to larger probe width (transverse to the scanning direction).

The Topas rectangular probes SYS 529 are designed for flow velocities of 31 - 47 cm/s and a particle counter volume flow rate of 28.3 l/min.

Protection factor measurement of operating rooms



ADD 536
details



Aerosol Distribution and Dilution System ADD 536.

The Aerosol Distribution and Dilution System ADD 536 is designed for measuring the protection factor of operating rooms according to [9]. In combination with an aerosol generator, the ADD 536 provides a test aerosol with defined and time stable source strength. Due to the freely placeable outlet ports, the aerosol is provided in equivalent amounts at 6 different measuring positions in the defined examination area. The variable dilution system built into the ADD 536 enables direct connection of a cleanroom particle counter. Visit the company website for further details on ADD 536.

Accessories

- flexible aerosol tubing
inner diameter: 6 mm ($1/4''$), 9 mm ($3/8''$)
- carry case for ATM and DIL
- trolley kit
- aerosol substance: DEHS, PAO

Specifications

Cleanroom qualification software CRQWin

The CRQWin software was developed according to the standards [6] and EU GMP (Good Manufacturing Practice) as an add-on to the PASWin software. It enables a systematic recording, saving, visualisation and evaluation of all data required for cleanroom qualification. Further advantages of the software are:

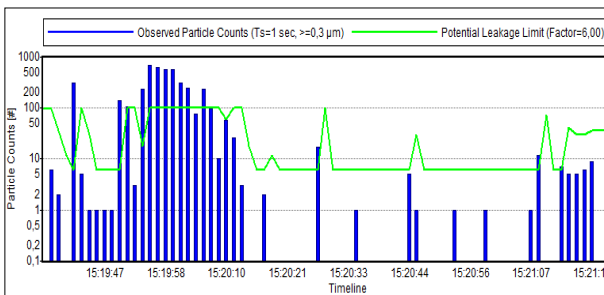
- time saving and error prevention
- simultaneous measurements with several particle counters
- multitasking Windows application

Supported tests

- confirmation of cleanroom classes
- recovery test
- filter leak test
- flow test for cleanrooms with turbulent mixing ventilation
- detection of the room differential pressure

Clean Room Qualification according to ISO					
Room/System	Norm Class	Norm Class	Status	Status	
	Target	Measured	Code	Text	
Room1	GMP C	GMP -	NOM	Not measured	
Demo-Room	ISO 8	ISO 8	PAS	Passed	
Demo-Room LAF1	ISO 9	ISO -	NOM	Not measured	

CRQWin software: Listing of various tests for the qualification of cleanroom facilities and cleanrooms.



CRQWin software: Particle counting in a certain period of time with suspected leakage limit.

Applied standards

The following standards and guidelines were considered in the design of the cleanroom test equipment set.

	standards/ guidelines	Extract of the title
[1]	VDI 2083 sheet 1-3	Testing of cleanroom systems
[2]	VDI 3491 sheet 1,2,15	Measurement of particles - preparation and dilution of test aerosols
[3]	ISO 21501-4	Light scattering airborne particle counter for clean spaces
[4]	EN 1822-4	High efficiency air filters (EPA, HEPA and ULPA) - Determining leakage of filter elements [scan method]
[5]	EN 29463-4	High-efficiency filters and filter media for removing particles in air - Test method for determining leakage of filter elements-Scan method
[6]	ISO 14644-1 ISO 14644-3	Cleanrooms and associated controlled environments - Test methods
[7]	EN 12469	Performance criteria for micro-biological safety cabinets
[8]	DIN 12980	Testing of cytostatic safety cabinets
[9]	EN 1946-4	Ventilation and air conditioning - Ventilation in buildings and rooms of health care

References

- [10] Große [2013] Cleanroom validation according to ISO 14644-3 using photometers and optical particle counters. ccr-Newsletter
- [11] Kuhn et al. [2013] Filterlecktest: Analyse von bewegten Probenahme-Sonden. reinraum online, 10. www.reinraum.de

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12 100 11908 TMS

Topas GmbH
Technologie-orientierte
Partikel-, Analysen- und Sensortechnik
Gasanstaltstraße 47 · D-01237 Dresden, GERMANY

Telefon +49 (351) 21 66 43 - 0
Fax +49 (351) 21 66 43 55
E-Mail office@topas-gmbh.de
Internet www.topas-gmbh.de

TOPAS-GMBH DE

PARTICLE UNDER CONTROL